



## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-481
<b>Regulation title</b>	Radiation Protection Regulations
<b>Action title</b>	Amend fingerprinting regulation to include NRC contact information
<b>Date this document prepared</b>	January 26, 2009

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulation 12VAC5-481-451 which became effective on October 3, 2008. This regulation requires radioactive material licensees that have certain quantities of radioactive materials of concern to have individuals who have unrestricted access to these materials fingerprinted and their names compared with those on the national terrorist screening database.

On November 10, 2008 the Nuclear Regulatory Commission (NRC) submitted a comment to VDH regarding 12VAC5-481-451. The comment stated "Virginia needs to add that the licensee must also call the NRC Headquarters Operations Center at 301-816-5100 to 12VAC5-481-451 (B)(2)(d), (B)(2)(a) 5 and (C)(6)."

The VDH anticipates entering into an agreement with the NRC for assuming regulatory authority of NRC's licensees located in Virginia on March 31, 2009. VDH is required to implement federal regulations and orders applicable to this regulatory activity.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

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On April 18, 2008, The State Board of Health voted to amend 12VAC5-481 (Radiation Protection Regulations) to include a new section (451) for increased controls and fingerprinting.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

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These regulations (12VAC5-481) are authorized by the Code of Virginia Sections 321.-229 et seq. Section 32.1-229 authorizes the Board of Health to: 1) Establish a program of effective regulation of sources of radiation for the protection of the public health and safety; 2) Establish a program to promote the orderly regulation of radiation within the Commonwealth, among the states and between the federal government and the Commonwealth and to facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized; and 3) Establish a program to permit maximum utilization of sources of radiation consistent with the public health and safety.

Refer to the following web site for viewing the statutory authority cited in Section 32.1-229 of the Code of Virginia: <http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229>

The Office of the Attorney General issued a statement that the proposed amendment had been reviewed and that the Department possesses the authority to promulgate this amendment pursuant to Chapter 6, Article 8 of Title 32.1 of the Code of Virginia.

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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The NRC submitted a comment to this agency stating: "Virginia needs to add that the licensee must also call the NRC Headquarters Operations Center at 301-816-5100 to 12VAC5-481-451 (B)(2)(d), (B)(2)(a) 5 and (C)(6)."

The NRC also revised the division name and address for submitting fingerprint records.

## Rationale for using fast track process

*Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

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To ensure continuity of regulatory activity, the NRC will require VDH to implement the December 5, 2007 NRC Order on the date of signing the state agreement with the NRC for the transfer of authority for regulating radioactive materials, set for March 31, 2009. This deadline cannot be met through the normal regulatory process that requires about two years to complete the adoption of a regulation. The fast track approach will reduce implementation to less than a year and allow the regulation to be in place on the date transfer of authority is projected to take place.

The regulation should be noncontroversial, since it was previously approved with no objections.

*Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

If there is an objection to the fast-track process, VDH will wait until the next revision of 12VAC5-481. We will also include the NRC notification requirement as a license condition.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)*

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This revision includes the NRC Headquarters Operation Office's phone number in three subsections. The NRC needs to be contacted along with this agency under certain situations. Also, the division name and address has changed for where licensees must submit their fingerprint records.

## Issues

*Please identify the issues associated with the proposed regulatory action, including:*

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

*If there are no disadvantages to the public or the Commonwealth, please indicate.*

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1.Primary advantages and disadvantages to the public:

The primary advantage to the public is that the fingerprinting requirement is more visible as a regulation than an order issued to specific radioactive material licensees and thus the public is assured that government is making an effort to prevent terrorists from obtaining radioactive materials for their activities.

There are no disadvantages to the public in promulgating the proposed regulation.

2. Primary advantages and disadvantages to the agency and Commonwealth:

Approving the amendment will address NRC’s comment ensuring the regulation is compatible and adequate to NRC when the Commonwealth signs an agreement with the NRC for this activity.

There are no disadvantages to the agency and the Commonwealth in promulgating the proposed regulation.

3. The NRC has implemented the requirements in the proposed regulation by an Order issued on December 5, 2007 and required compliance by June 2, 2008. VDH will need to have these requirements in place on date of agreement with the NRC.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no requirements in the proposed regulation that are more restrictive than the applicable federal requirements.

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

None

**Regulatory flexibility analysis**

*Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

1. The proposed regulation cannot be less restrictive than the NRC Order.
2. The proposed regulation cannot become effective until the Commonwealth enters into an agreement with the NRC on March 31, 2009. All licensees needed to comply with this requirement under federal jurisdiction by June 2, 2008.
3. The proposed regulation is required to be identical to the NRC Order. There is no provision made for specific performance standards for small business licensees.
4. The proposed regulation is required to be identical to the NRC Order. There is no provision made to exempt small business licensees from these requirements.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b>	The funding for this activity will be supported by licensing fees from the radioactive material users. Fund 0280. The implementation of the fingerprinting requirement will be borne by the NRC until an agreement is signed with the NRC. Thereafter the annual cost to ensure compliance will add less than \$1,000 to the cost of inspections annually.
<b>Projected cost of the regulation on localities</b>	None
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	The affected radioactive materials licensees are those that have large quantities of certain radioactive materials and include medical facilities, engineering and gas drilling firms.
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are 25 radioactive material licensees in Virginia that are impacted by the NRC Order and whose licenses would transfer to Virginia in an agreement with the NRC. About 12 are small businesses.
<b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b>	The cost of an FBI criminal history records check and fingerprinting is about \$100 per employee. The costs of reporting, recordkeeping, and other administrative costs are unknown; however, should be less that \$100 annually.

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

There are no other alternatives.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The proposed changes would not have a direct impact on the institution of the family and family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
12VAC5-481-451			<p>d. After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the agency at (804) 864-8150 during normal business hours and (804) 674-2400 after hours <u>and the NRC HQ Operations Center at (301) 816-5100.</u></p> <p>5) Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or missing, the licensee shall immediately notify the agency at (804) 864-8150 during normal working hours and (804) 674-2400 after hours <u>and the NRC HQ Operations Center at (301) 816-5100.</u> If after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material shall be determined missing</p>

			<p>and the licensee shall immediately notify the agency at (804) 864-8150 during normal working hours and (804) 674-2400 after hours <u>and the NRC HQ Operations Center at (301) 816-5100.</u></p> <p>d. All fingerprints obtained by the licensee pursuant to this section must be submitted to the NRC (<del>Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program, Mail Stop T-6E46, Rockville, MD 20852</del>) (<u>Office of Administration, Security Processing Unit, Mail Stop TWB-05 B32M, US NRC, Washington, DC 20555-0012</u>) for transmission to the FBI. Additionally, the licensee shall submit a certification of the trustworthiness and reliability of the Trustworthy &amp; Reliability (T &amp; R) Official as determined in accordance with subdivision 5 of this subsection. (See the NRC's website at <a href="http://www.nrc.gov">www.nrc.gov</a> for more information on submitting fingerprints, including pricing and address changes). The licensee shall review the information received from the FBI and consider it, in conjunction with the trustworthiness and reliability requirements of subdivision B 1 of this section, in making a determination whether to grant unescorted access to certain radioactive materials;</p> <p>6. The licensee shall notify the agency at (804) 864-6168 <u>and the NRC HQ Operations Center at (301) 816-5100</u> within 24 hours if the results from an FBI identification and criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Data Base.</p>
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Enter any other statement here